IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES, ET AL., EX REL. MARK RADCLIFFE,	)	
	)	Case No. 1:05CV00089
Plaintiffs,	)	
	)	**OPINION**
v.	)	
	)	By: James P. Jones
PURDUE PHARMA L.P., ET AL.,	)	Chief United States District Judge
	)	
Defendants.	)	

Mark T. Hurt, Abingdon, Virginia, and Paul W. Roop, II, Beckley, West Virginia, for Mark Radcliffe; Howard M. Shapiro and Jennifer M. O'Connor, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, D.C., and Howard C. McElroy, McElroy, Hodges, & Caldwell, Abingdon, Virginia, for Purdue Pharma L.P. and Purdue Pharma, Inc.

In this qui tam action, the defendants have moved to dismiss on several grounds, including the jurisdictional bar based on prior public disclosures of the alleged false claims, the execution of a pre-filing general release by the relator, and a failure to plead fraud with particularity under Rule 9(b). For the reasons set forth below, I deny the former two grounds of dismissal, but I will grant the motion under Rule 9(b), with leave to amend.[1]

[1] Certain sealed material has been redacted from the publicly released copy of this opinion. Redactions are denoted in brackets. The parties have been provided with the sealed copy.

I. BACKGROUND.

In this action brought under the qui tam provisions of the False Claims Act ("FCA"), 31 U.S.C.A. §§ 3729-3733 (West 2003 & Supp. 2008), and analogous state statutes, the relator Mark Radcliffe alleges that the defendants, Purdue Pharma, L.P. and Purdue Pharma, Inc. (collectively, "Purdue"), misrepresented to physicians the relative potency of Purdue's controlled-released, oxycodone-based pain medication, OxyContin, which resulted in federal and state agencies, such as Medicaid, paying more than was necessary in reimbursement. Radcliff is a former sales representative and manager at Purdue, who left its employment shortly before he filed the present suit.

This action was stayed for some time at the request of the federal government, which eventually declined to intervene, along with all of the thirteen state governments named in the Complaint.[2] Purdue then filed the present Motion to Dismiss, seeking a dismissal on the grounds that Radcliffe's claims are based on publicly disclosed information rather than information he discovered; that Radcliffe

[2] Radcliffe initially filed his Complaint, disclosing his allegations to the government, on September 27, 2005. The case was stayed for over a year and a half until the government declined to intervene on May 8, 2007. During this time the government was conducting a criminal investigation of Purdue's marketing of OxyContin, eventually resulting in guilty pleas in this court by a related company and three of Purdue's top executives. *See United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569, 576 (W.D. Va. 2007) (accepting plea agreements).

has released Purdue from the claims; and that the Complaint fails to adequately allege fraud as required by Federal Rule of Civil Procedure 9(b).[3]

As to the defense that Radcliffe had released Purdue from the claims, I decided to treat the Motion to Dismiss as one for summary judgment in accord with Federal Rule of Civil Procedure 12(d). Further limited discovery and briefing was allowed as to that issue.

All of the issues are now ripe for decision and will be discussed sertiam.

II. THE PUBLIC DISCLOSURE BAR.

The FCA provides that there is no subject matter jurisdiction in a case where the claim is

> based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

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[3] Purdue initially contended that the Complaint failed to state a claim because Radcliffe's allegations merely showed "a scientific dispute . . . regarding the relative potency of oxycodone." (Mem. Supp. Defs.' Mot. Dismiss 20.) Purdue has withdraw that argument, including its related Request for Judicial Notice. (Reply Supp. Defs.' Mot. Dismiss 35.) Because of my disposition of the case, I do not reach Purdue's arguments that some of the claims may be barred by the applicable statute of limitations or that some of state causes of action are procedurally barred.

31 U.S.C.A. § 3730(e)(4)(A). The purpose behind this bar, of course, is to "stifl[e] parasitic lawsuits." *United States ex rel. LaCorte v. Wagner*, 185 F.3d 188, 191 (4th Cir. 1999).

Because the public disclosure bar involves the jurisdiction of the court, it must be determined first, before proceeding to any other questions. *United States ex rel. Wilson v. Graham County Soil & Water Conservation Dist.*, 528 F.3d 292, 309 (4th Cir. 2008). In deciding a jurisdictional challenge, the court must determine the facts based on the evidence submitted. *Id*. at 308. The plaintiff has the burden of showing that the court has subject matter jurisdiction. *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982).

The facts on which I have determined jurisdiction are as follows.

In his job marketing OxyContin to physicians, the relator Radcliffe became familiar with claims made by Purdue about the medication's relative cost and potency. Specifically, in his sales representative training, he alleges that he was taught that there was a 2:1 equianalgesic ratio between OxyContin and MS Contin, a rival pain medication containing morphine, making OxyContin twice as potent and, as a result, cheaper per dose than MS Contin. Training materials included this claim and Purdue encouraged sales representatives to emphasize this cost difference when speaking with physicians.

Radcliffe encountered skepticism from physicians he spoke with regarding OxyContin's relative cost and potency. Several of these physicians directed Radcliffe to specific sources in the scientific literature to show that the correct equianalgesic ratio between MS Contin and OxyContin was closer to 1:1, meaning that OxyContin was less potent and more expensive than Purdue claimed. These sources supported an equianalgesic ratio of 1:1 for chronic or around-the-clock dosing, but acknowledged that single dose studies supported the 2:1 ratio. *See* Agency for Health Care Policy & Research, Public Health Serv., U.S. Dept. of Health & Human Servs., *Clinical Practice Guideline: Acute Pain Management: Operative or Medical Procedures and Trauma*, app. C2 (Feb. 1992) ("Clinical Practice Guideline"); *United States Pharmacopeia–Dispensing Information* 2238 tbl. 2 (16th ed 1996) ("USP"); Robert G. Twycross, *Opioids*, in *Textbook of Pain* 943, 953 tbl. 49.7 (Patrick D. Wall & Ronald Mezack eds. 3d ed. 1994) ("Textbook of Pain"). Because MS Contin and OxyContin were designed for chronic dosing, these physicians believed the 1:1 equianalgesic ratio was the appropriate one.

When Radcliffe raised this concern to supervisors, he was told that by approving the OxyContin package inserts, which contained the 2:1 equianalgesic ratio as a starting conversion that could later be adjusted by doctors, the U. S. Food and Drug Administration ("FDA") had approved that ratio. He was also told that

Purdue's decision to rely on the 2:1 ratio, despite published articles indicating that the 1:1 ratio was more appropriate for OxyContin's approved use, was based on safety concerns, that is, it was better for doctors to start with a lower dose and adjust upward if necessary. These responses did not address the cost implications that concerned Radcliffe.

In his qui tam Complaint,[4] Radcliffe alleges that Purdue falsely and fraudulently, through its salesmen's oral misrepresentations and the information presented in the OxyContin package insert, asserted to physicians and other decision-makers that there was a 2:1 equianalgesic ratio between OxyContin and MS Contin, and, thus, that OxyContin was cheaper per dose than MS Contin. He alleges that this was done to induce physicians to prescribe OxyContin and other decision-makers to purchase or authorize the purchase of OxyContin. He submits that each OxyContin prescription submitted to the government for reimbursement constitutes a false claim under the FCA and the analogous state statutes, because the product distributed had only half the potency that physicians and decision-makers had been led to believe it

[4] Radcliffe has amended his Complaint three times since it was originally filed, so that Purdue's Motion to Dismiss actually relates to the Third Amended Complaint filed June 5, 2007. For the purposes of addressing the public disclosure issue, the Complaint and the Third Amended Complaint contain the same claims and neither party has indicated that any relevant public disclosures were made between the date the Complaint was file and the date that the Third Amended Complaint was filed. For convenience, references herein to the "Complaint" shall include the most recent version.

possessed. In his Complaint, Radcliffe cites the three publications shown to him by the physicians—the Clinical Practice Guideline, the USP, and the Textbook of Pain—to support the correctness of the 1:1 ratio. He also refers to, but does not cite, a single-dose study supporting the 2:1 ratio that he was told about by his supervisors at Purdue. It is unclear from the Complaint and subsequent filings whether Radcliffe ever read this study or merely heard about it from the supervisors and physicians.

The Fourth Circuit follows a three-step approach in determining whether the public disclosure bar applies. *Wilson*, 528 F.3d at 299. First, was there a public disclosure? If so, was the qui tam action based on the public disclosure? Finally, if the action was based on the public disclosure, was the relator an original source? *Id*. Under § 3730(e)(4), an action is properly dismissed for lack of subject matter jurisdiction only if there was a public disclosure on which the relator's allegations were based and that relator is not an original source. *Id.*

Section 3730(e)(4)(A) provides an exclusive list of sources that may give rise to a public disclosure that will strip a court of subject matter jurisdiction: "disclosures in (1) criminal, civil, or administrative hearings; (2) congressional, administrative, or Government [Accountability] Office reports, hearings, audits, or investigations; and (3) the news media." *Wilson*, 528 F.3d at 300-01 (alternations and internal quotations omitted); *see Eberhardt v. Integrated Design & Constr., Inc*., 167 F.3d 861, 870 (4th

Cir. 1999). Disclosures made in other public forums do not implicate the public disclosure bar. *Id.*

In addition to this source requirement, the disclosure must have been of the "allegations or transactions" on which the qui tam action is based, not merely of information used by the qui tam relator. 31 U.S.C.A. § 3730(e)(4)(A); *see United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654-55 (D.C. Cir. 1994); *United States ex rel. Rabushka v. Crane Co.*, 40 F.3d 1509, 1512-14 (8th Cir. 1994). Generally, this does not require that the disclosure be of the specific allegations brought by the relator, but instead the disclosure must put the government on notice of the likelihood of fraudulent activity. *United States ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386, 389 (6th Cir. 2005); *see Springfield*, 14 F.3d at 655. To meet this requirement, it is sufficient that there have been either (1) disclosures of both a false state of facts and a true state of facts (not necessarily from the same source) so that fraud is implied; or (2) disclosure of an allegation of fraud, regardless of the specificity of the allegation. *Gilligan*, 403 F.3d at 389; *see also Springfield*, 14 F.3d at 655; *United States ex rel. Mistick PBT v. Hous. Auth. of Pittsburgh*, 186 F.3d 376, 385 (3d Cir. 1999); *Rabushka*, 40 F.3d at 1514.

Purdue argues that in the present case, the following constitute public disclosures: (1) published scientific articles and reference materials cited in the

Complaint, which support an equianalgesic ratio of 1:1 between MS Contin and OxyContin for repeated dosing, but note the existence of single-dose studies that support a ratio of 2:1; (2) a single-dose study that supports an equianalgesic ratio of 2:1 and a published article and an abstract reporting the results of this study; (3) other materials published in scientific journals, which support the 2:1 equianalgesic ratio for longer-term use, that Purdue argues Radcliffe would have been familiar with in his employment; and (4) the OxyContin package insert, which was approved by the FDA and was, at one time, available on Purdue's web site.

The published scientific articles and reference materials cited by Radcliffe in his Complaint—the Clinical Practice Guideline, the USP, and the Textbook of Pain—fall within the "news media" category of § 3730(e)(4)(A) and constitute public disclosures. The term "news media" includes scholarly, scientific, and technical periodicals, including trade journals, because, like newspapers, these sources disseminate information to the public in a periodic manner. *United States ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d. 458 (S.D.N.Y.), *aff'd*, 53 F. App'x 153 (2d Cir. 2002); *see also Gold v. Morrison-Knudsen* Co., 68 F.3d 1475, 1476-77 (2d Cir. 1995); *State ex rel. Grayson v. Pac. Bell Tel. Co.*, 142 Cal. App. 4th 741, 754-55 (Cal. Ct. App. 2006). The three articles cited by Radcliffe were published in scientific and medical reference periodicals that

distribute new or updated material on a periodic basis. Thus, I find that these constitute public disclosures in the news media.

In his Complaint, Radcliffe references, but does not cite, a single-dose potency study that his supervisors told him supported an equianalgesic ratio of 2:1. While the results of this study were not published until 1999, an abstract including the 2:1 equianalgesic ratio was published in 1996. *See* Robert F. Kaiko et al., *Analgesic Onset and Potency of Oral Controlled-Release (CR) Oxycodone and CR Morphine*, 59 (2) Clin. Pharmacol. & Therapeutics 130 [Abstract PI-4] (1996); G.B. Curtis et al., *Relative Potency of Controlled-Release Oxycodone and Controlled-Release Morphine in Postoperative Pain Model*, 55 Eur. J. Clin. Pharmacol. 425, 428 (1999). Both were published in scientific periodicals. To the extent that Radcliffe based the allegations in his Complaint on either the published abstract or the published article, these constitute public disclosures in the news media.

Radcliffe argues that the published results of the single-dose study are not public disclosures under § 3730(e)(4)(A) because these were published in a foreign periodical. He relies on *United States ex rel. Yannacopolous v. General Dynamics*, 315 F. Supp. 2d 939, 949 (N.D. Ill. 2004), which held that newspaper articles published in Greek in the Greek press did not constitute disclosures to the American public. It reasoned that "[t]here is no public disclosure to the American public when

information is divulged in a foreign publication, especially if published in a foreign language." *Id.* While the 1999 article was published in *European Journal of Clinical Pharmacology*, it was authored by scientists in the United States and written in the English language. Given the international nature of the scientific community, there is no indication that the publication of this article in a foreign scientific journal makes it any less accessible to the American public than if it were published in a scientific journal located in the United States. Regardless, the 1996 abstract was published in *Clinical Pharmacology & Therapeutics*, a scientific journal headquartered in Alexandria, Virginia. To the extent that Radcliffe derived the allegations in his Complaint from either of these sources, these will be considered public disclosures in the news media.

Purdue next argues that other scientific publications supporting an equianalgesic ratio of 2:1, not only for single or intermittent dosing but also for longer-term use, are public disclosures because "[a]s a Purdue sales representative and supervisor, Radcliffe would have been trained on and intimately familiar with many Purdue articles endorsing a 2:1 equianalgesic potency ratio." (Defs.' Reply to Resp. to Mot. Dismiss 11.) Purdue does not claim definitively that Radcliffe actually knew of or relied on the particular scientific articles it cites. However, to the extent

that Radcliffe actually did base his qui tam allegations on these articles, these will be considered public disclosures in the news media.

Finally, Purdue argues that the OxyContin package insert is a public disclosure, either in the news media or from an administrative investigation. The package insert recommends a starting conversion rate between OxyContin and MS Contin of 2:1, which can be reassessed based on a patient's reaction to the dosage. It further states that OxyContin is "indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time." (Mem. Supp. Defs.' Mot. Dismiss, Exs. C & D.) In addition to its inclusion in OxyContin packages, the package insert is available on Purdue's publically-assessable web site.

Purdue cites *United States ex rel. Doyle v. Diversified Collection Services, Inc.*, No. 2:04 CV 053, 2006 WL 3834407, at *3 (S.D. Ohio Dec. 29, 2006), for the proposition that publication on the Internet constitutes a public disclosure under § 3730(e)(4)(A). This case briefly mentions several sources— "two previously filed lawsuits against defendant, as well as an Internet web page and a Pittsburgh Post-Gazette article"—and summarily concludes that "these constitute public disclosures." *Id.* The opinion makes no mention of what type of web page this is or whether it bears any resemblance to a traditional periodical. For instance, this web page could

be affiliated with a news publication and, as such, would be updated regularly and would disseminate information to the public in a periodic manner. Its affiliation with a traditional news outlet or periodical or its identification as an online news outlet also identifies to the public that it is a place where news or periodical information on a particular topic can be found. Given the vast array and varying credibility of web pages on the Internet, I am not ready to conclude that anything posted online would automatically constitute a public disclosure within the meaning of § 3730(e)(4)(A).

Looking at the specific web page cited by Purdue, it appears that on July 18, 2001, the OxyContin package insert was posted to a section of Purdue's web page entitled "News & What's New." The package insert is currently posted to a section of Purdue's web page devoted to package inserts. Despite the labeling of the 2001 page, I find that this is not analogous to a traditional news outlet or periodical or even a trade journal because it involves information disseminated by one company about its own products, rather than a news organization or industry group disseminating information of general or specialized interest. Instead both the 2001 posting and the current posting of the OxyContin package insert seem more akin to a corporate report or a press release. While corporate reports have been held insufficient to implicate the jurisdictional bar of § 3730(e)(4)(A), *Rabushka*, 40 F.3d at 1514 n.2, press releases have been deemed public disclosures within the meaning of the statute,

United States ex rel. Kennedy v. Aventis Pharms., Inc., 512 F. Supp. 2d 1158, 1164-65 (N.D. Ill. 2007). Although the 2001 posting of the OxyContin package insert could be considered either a corporate report or a press release, because it was posted on a web page entitled "News & What's New" and because other items on the page resemble press releases, I will consider the OxyContin package insert a public disclosure in the news media. Accordingly, I do not address Purdue's second argument that the package insert is a public disclosure from an administrative investigation.

In summary, Purdue argues that the public disclosures in these scientific articles and in the OxyContin package insert amount to a disclosure of the fraudulent transactions alleged in Radcliffe's qui tam suit and put the government on notice of the potential fraud. Specifically, Purdue argues that the single-dose study, other scientific articles, and its OxyContin package insert, which recommend an equianalgesic ratio of 2:1 between OxyContin and MS Contin, represent the alleged "false" state of facts, while scientific sources cited by Radcliffe in the Complaint, which recommend a ratio of 1:1, represent the "true" state of facts. Together, Purdue argues, these create an implication of fraud sufficient to put the government on notice. While these public disclosures do demonstrate some disagreement or debate

over the appropriate equianalgesic ratio, I am not convinced that they sufficiently raise the specter of fraud.

In *Rabushka*, a shareholder filed suit alleging that his conversations with company executives demonstrate that they fraudulently understated unfunded pension liability and spun off one of the company's components in order to shift responsibility for the pensions to another entity. 40 F.3d at 1510. Prior public disclosures revealed the spin off, the company's problems with the unfunded pension liability, and eventually, the company's bankruptcy. *Id.* at 1512. In holding that these disclosures did not raise the inference that company executives intentionally and fraudulently understated the pension problem or engineered the spin off in an attempt to avoid liability, the court noted that none of the disclosures imputed any bad faith or wrongdoing to the company and instead were "optimistic" about the company's future. *Id.* at 1512-13. Further, this shareholder-relator was the first to allege that company executives knew of the extent of the underfunding at the time of the spin off and that the liability was large enough to place the company in jeopardy of failing. *Id.* at 1513. While the prior public disclosures included information that was true, they did not reveal the "true" state of facts regarding the executives' knowledge or intentions. Because the information contained in the disclosures was insufficient to imply fraud, it did not trigger the jurisdictional bar. *Id.* at 1513-14.

Likewise, the prior public disclosures reveal that there was contradicting scientific evidence as to the relative potency of OxyContin to MS Contin, but they do not imply fraud. Some studies recommended an equianalgesic ratio of 1:1, particularly for chronic, around-the-clock dosing; they acknowledged studies that recommended a ratio of 2:1 for single or intermittent doses. While the OxyContin package insert recommends the 2:1 conversion ratio as a starting point for doctors switching patients from MS Contin to OxyContin, it also suggests the need to reevaluate based on each individual patient's response to the new medication. Finally, Purdue submits that Radcliffe should have known of, and did not deny knowledge of, other studies supporting the 2:1 ratio for longer-term use.

Taken together, these disclosures reveal disagreement in the scientific community, but do not raise an inference of fraud. While these disclosures all reveal true information regarding the current state of the scientific debate, they do not reveal the "true" state of facts regarding the fraud alleged by the relator, that is, that Purdue used the 2:1 ratio despite knowing that it was inaccurate in order to mislead physicians and other decision-makers regarding the relative cost and potency of OxyContin. These disclosures suggest legitimate scientific debate and disagreement regarding the correct equianalgesic ratio, rather than any fraudulent intent on the part of Purdue. If anything on the record suggests fraud with respect to the relative cost

and potency, it is the relator's statements regarding his experiences in being trained to market OxyContin and his questioning of his supervisors about the relative potency issue, as well as the internal training materials that explained how to address the relative cost issue with physicians.

Because I find that these scientific articles and the OxyContin package insert, taken together, do not disclose or imply fraud, and, thus, do not constitute a public disclosure of the allegations or transactions within the meaning of § 3730(e)(4)(A), I need not address the extent to which Radcliffe based his allegations on these materials, nor whether he was an original source.

I am troubled by the fact that Radcliffe's behavior, in waiting until the Department of Justice had already begun a criminal investigation into other allegations of marketing fraud committed by Purdue, before filing his qui tam action, suggests that he is an opportunistic relator. While allegations of fraud were known to the Department of Justice, they had not been publically disclosed within the meaning of § 3730(e)(4)(A). This subsection includes disclosures made in "criminal hearings," as well as those made in "administrative investigations," but I cannot see that, nor have the parties asserted that, either of these classifications applies to the current situation.

It has been held that disclosures made directly to relevant government officials, rather than to the public, can constitute public disclosures in administrative investigations when the disclosure is made "to a competent public official" "who has managerial responsibility for the very claims being made." *United States v. Bank of Farmington*, 166 F.3d 853, 861 (7th Cir. 1999). Had the substance of the relator's allegations been disclosed to an appropriate employee at the FDA with the authority to investigate these claims, that might have constituted a disclosure in an administrative investigation. However, that is not the situation before me.

For these reasons, I find that this court his subject matter jurisdiction over the Complaint.

III. THE RELEASE DEFENSE.

Purdue contends that Radcliffe released the claim made in his Complaint in the course of a settlement agreement with Purdue when he left its employment. The facts surrounding this defense have been developed in the summary judgment record.

In his employment with Purdue between 1996 and 2005, Radcliffe was responsible for marketing OxyContin to individual physicians and became familiar with Purdue's marketing claims about OxyContin's relative cost and potency,

including the claim that there is a 2:1 equianelgesic ratio between OxyContin and MS Contin.

As early as 1996, Radcliffe found that some of the physicians he spoke to were skeptical of this 2:1 ratio. When he raised the issue his supervisor assured him that the 2:1 ratio was correct. Apparently Radcliffe later experienced more doubts because in 2004 he sought legal advice and in January 2005 he anonymously contacted Randy Ramseyer, an Assistant United States Attorney for the Western District of Virginia, to gauge the government's interest in a claim against Purdue. It is undisputed that Radcliffe did not identify the nature of his allegations against Purdue in the course of these conversations with Ramseyer.

In January and February of 2005 Radcliffe sent emails to several officers and directors of Purdue, using the alias "John Femaledeer." In these somewhat rambling and incoherent emails, he warned Purdue that he was considering a qui tam suit, detailed his allegations, and offered to settle in exchange for an investment by Purdue in a project he was contemplating. He later retracted that offer after being informed by a lawyer that he could not settle a qui tam suit.

Several months later, Purdue restructured its sales force and Radcliffe was offered the option of transferring positions, which he declined, or termination with

an extended severance package. On August 1, 2005, he signed a severance agreement, which included a general release of all claims against Purdue.[5]

Radcliffe then filed his qui tam Complaint on September 27, 2005. It is undisputed that Radcliffe did not disclose the nature of his qui tam allegations to the government prior to the filing of his Complaint.[6]

During this period or time, the government was conducting its own comprehensive investigation into Purdue's manufacturing, marketing, and

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[5] The Agreement and General Release that Radcliffe signed contained the following language:

> Employee, of Employee's own free will, knowingly and voluntarily releases and forever discharges the Company, its affiliates, Associated Companies, subsidiaries, divisions, successors and assigns and the employees, officers, directors, owners, stockholders, trustees, predecessors, attorneys and agents thereof (collectively referred to as "The Purdue Associated Entities"), of and from any and all liability to Employee for actions or causes of action, suits, claims, charges, complaints, contracts (whether oral or written, express or implied from any source), and promises, whatsoever, in law or equity, which, Employee, Employee's heirs, executors, administrators, successors, and assigns (referred to collectively throughout this Agreement as "Employee") ever had, may now have or hereafter can, shall or may have, against The Purdue Associated Entities as of the date of the execution of this Agreement, including all unknown, undisclosed and unanticipated losses, wrongs, injuries, debts, claims, or damages to Employee, for, upon, or by reason of any matter, cause or thing whatsoever.

(Mem. Supp. Defs.' Mot. Dismiss, Ex. A-5, ¶ 4(a).)

[6] Ramseyer recalls receiving a telephone call from a West Virginia attorney regarding a possible qui tam suit against Purdue at some point prior to September 27, 2005. However, he states that no details of the alleged misconduct were given and the attorney did not identify the name of his client.

distribution of OxyContin. According to Assistant United States Attorney Rick A. Mountcastle, "one area of investigation concern[ed] whether Purdue falsely marketed OxyContin as being twice as potent as morphine and, accordingly, less expensive than MSContin." (Mountcastle Decl. ¶ (c).) He further stated that "the 2:1 comparison of OxyContin to MSContin [wa]s one of the areas under investigation." (*Id.* ¶ (f)(2).) Beginning in 2002 and continuing for the next several years, the government sought millions of documents from Purdue and conducted hundreds of interviews, some of which pertained to the relative potency and cost of OxyContin and MS Contin.

[Redacted].

On June 23, 2005, the government requested that Purdue identify the author and source of different versions of a document **[Redacted]** already in the government's possession, **[Redacted]**.

On June 24, 2005, a conversation took place between Department of Justice attorney Barbara Wells and attorney Michael Scheininger, who represented several Purdue employees, about topics that would be discussed when those employees testified before the grand jury investigating Purdue. According to Scheininger, Wells mentioned several times that she wished to ask these witnesses about the dispute over the relative potency of OxyContin and MS Contin, among other topics, explaining

that this related to the marketing and cost implications of the relative potencies. These employees were indeed asked questions pertaining to the relative potency issue during their grand jury appearances on July 20, 2005.

In mid-July 2005 the government reviewed and flagged numerous documents in the possession of four Purdue employees, **[Redacted]**. No list was kept of the documents reviewed or flagged, but according to the declaration of one of Purdue's outside counsel these included documents about the dispute over the relative potency of OxyContin and MS Contin. Counsel also stated that on July 28, 2005, she spoke to an attorney from the Department of Justice who expressed an interest in using electronic searches to identify documents **[Redacted]**.

Also on July 28, the government issued a subpoena for Michael Cullen, **[Redacted]**; he was later asked during his grand jury testimony about the relative potency issue. By this time, the government had also begun drafting Grand Jury Subpoena 513, which included requests for all documents discussing relative analgesic potency or safety of OxyContin and MS Contin.

Following Radcliffe's execution of the general release on August 1, 2005, the government's investigation continued. On August 2, 2005, a subpoena was issued commanding Radcliffe to appear before the grand jury. In September, the Department of Justice contacted Purdue's outside counsel with electronic search terms designed

to capture documents **[Redacted]**. These terms included those related to the issues of relative potency and cost, as well as those that seem more related to the potential for abuse or the effects of withdrawal. Modification of these search terms occurred in December, 2005.

On September 27, 2005, Radcliffe filed his qui tam Complaint. He attached to the complaint at least one document already in the government's possession: an "Answer Guide" used to train sales representatives, which urged them to emphasize OxyContin's higher potency and lower cost compared to MS Contin. Radcliffe was interviewed by law enforcement agents on October 28, 2005. Radcliffe was asked about the marketing of OxyContin as it related to the potential for addiction, but he was not asked about the relative cost and potency issue.

The government's investigation continued and on December 5, 2005, AUSA Mountcastle moved to stay Radcliffe's qui tam suit pending the government's ongoing investigation. Mountcastle argued that the suit could hinder the investigation because while Purdue was aware of the investigation "no mention ha[d] been made that the 2:1 comparison of OxyContin and MSContin [was] one of the areas under investigation." (Mountcastle Decl. ¶ (f)(2).) Further, Radcliffe was cooperating with the government and was scheduled to be a grand jury witness.

Unsealing the Complaint or allowing the suit to proceed would make a portion of the grand jury's pending investigation public.

After the present qui tam suit was stayed, the government's investigation continued. Radcliffe was interviewed a second time in September 2006 and asked about the misleading promotion of OxyContin. He was not asked about the relative cost or potency of OxyContin and MS Contin, nor was he asked about the equianalgesic ratio of these two drugs.

The stay was lifted in late 2006, and the government chose not to intervene on May 8, 2007. On May 10, 2007, the government filed a criminal information against a related Purdue entity and several Purdue executives, along with executed plea agreements for all the criminal defendants. Although the criminal charges did relate to the misbranding of OxyContin, these charges focused on Purdue's marketing of OxyContin as "less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications." (Information ¶ 20, *United States v. Purdue Frederick Co.*, No. 1:07-CR-00029 (W.D. Va.)) None of the misbranding charges pertained to the relative cost and potency issue. The plea agreements included settlement of certain of the government's civil claims, but not of Radcliffe's qui tam suit.

Summary judgment is appropriate only if there are no material facts in dispute and the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett,* 477 U.S. 317, 322 (1986). All reasonable inferences are "viewed in the light most favorable to the party opposing the motion." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 587 (1986) (quotations and citations omitted). Once the moving party has met its burden, "the nonmoving party must come forward with 'specific facts showing that there is a *genuine issue for trial.*'" *Matsushita,* 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)).

While the issue of whether a general release is enforceable to bar a subsequent qui tam action has not been addressed by the Fourth Circuit, the framework established by the Ninth Circuit in *United States ex rel Green v. Northrop Corp.*, 59 F.3d 953 (9th Cir. 1995), and *United States ex rel Hall v. Teledyne Wah Chang Albany*, 104 F.3d 230 (9th Cir. 1997), has been applied by subsequent federal courts faced with the issue. *See United States ex rel. Gebert v. Transp. Admin. Servs.*, 260 F.3d 909, 916 (8th Cir. 2001); *United States ex rel. Bahrani v. Conagra, Inc.*, 183 F. Supp. 2d 1272, 1275-78 (D. Colo. 2002); *United States ex rel. DeCarlo v. Kiewit/AFC Enters., Inc.*, 937 F. Supp. 1039, 1043-47 (S.D.N.Y. 1996).[7]

[7] Purdue urges the court to consider pre-*Green* cases *Virginia Impression Products Co. v. SCM Corp.*, 448 F.2d 262 (4th Cir. 1971), and *Coleson v. Inspector General of the Department of Defense*, 721 F. Supp. 763 (E.D. Va. 1989). However, neither case discusses

Green involved a general release between an employer and a terminated employee, who later filed a qui tam suit against that employer. *Green*, 59 F.3d at 956. After the action was filed, the United States investigated the qui tam relator's allegations, but ultimately chose not to intervene. *Id.* at 956-57. The district court granted summary judgment to the defendants who argued that, as part of the release, the relator had bargained away his right to bring the qui tam suit and as a result could not demonstrate any personal stake in the outcome sufficient to satisfy Article III standing. *Id.* The Ninth Circuit reversed, holding that a pre-filing release entered into without the government's knowledge or consent is not enforceable to bar a subsequent qui tam action because that would impair a substantial public policy.

In doing so, the court relied on the test set forth in *Town of Newton v. Rumery*, 480 U.S. 386 (1987),[8] that "'a promise is unenforceable if the interest in its

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the policy implications of enforcing a release in the context of the FCA. In *Virginia Impression Products*, which was decided before *Green* and also before *Rumery*, the Fourth Circuit chose to enforce a release to bar a subsequent antitrust claim. The court found no statutory or policy reasons to prevent enforcement of the release. Although antitrust cases are similar to qui tam suits in that the government relies on the enforcement efforts of private parties, the policy implications and economic incentives differ. *Coleson*, which was decided prior to *Green* but after *Rumery*, involved a claim brought under the anti-retaliation provisions of the FCA, rather than a qui tam claim brought on behalf of the government. While the court reasoned that the enforceability of the release should be governed by federal law because it arose under federal law, the court did not address any of the public policy concerns associated with qui tam suits or the FCA.

[8] To reach this decision, the Ninth Circuit first evaluated the statutory scheme of the FCA and determined that while Congress had addressed the ability of parties to settle post-filing, it left open the enforceability of pre-filing releases. *Green*, 59 F.3d at 959. As the

enforcement is outweighed in the circumstances by a public policy harmed by enforcement of the agreement.'" *Green*, 59 F.3d at 962 (quoting *Rumery*, 480 U.S. at 392).[9] The Ninth Circuit determined that enforcement of the release would impair

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release involved a statutorily-conferred federal right, the Ninth Circuit turned to federal common law to fill this "gap" in the statutory scheme. *Id.* at 960. Because of the potential in this area for state law to impair federal rights, the possibility of forum-shopping, and the unlikeness that uniform federal rule would disrupt commercial relationships predicated on state law, the Ninth Circuit chose to craft a uniform federal rule, rather than apply state law. *Id.* at 961 (applying the three-part test in *United States v. Kimbell Foods, Inc.*, 440 U.S. 715 (1979)). Once it decided to fashion a uniform rule on the enforceability of pre-filing releases, the Ninth Circuit turned to *Rumery*, 480 U.S. at 392, to structure its discussion of competing policy concerns. *Green*, 59 F.3d at 962. This line of reasoning has been adopted by the Eighth Circuit, *Gebert* , 260 F.3d at 916, and the Southern District of New York, *DeCarlo*, 937 F. Supp. at 1043-46. It has been noted that "[c]ourts have applied *Rumery* to a broad spectrum of pre- and post-filing releases of *qui tam* claims entered into without the United States' knowledge or consent." *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 481 F. Supp. 2d 815, 818 (S.D. Tex. 2007).

[9] The Ninth Circuit also relied on *Davies v. Grossmont Union High School District*, 930 F.2d 1390 (9th Cir. 1991), which builds upon the *Rumery* test. *Davies* requires that a determination be made as to whether a substantial public interest would be impaired by enforcement of the agreement. If not, then the court balances "all the factors that bear on whether 'the public interest in enforcement of the agreement outweigh the policies furthered by non-enforcement.'" *Green*, 59 F.3d at 962 (quoting *Davies*, 930 F.2d at 1396). If a substantial public interest would be impaired, the court need not engage in the *Rumery* balancing test unless there is an articulated reason favoring enforcement aside from the "'interest in the settlement of litigation,'" as that "'cannot by itself outweigh a substantial public interest on the other side of the scales.'" *Id.* at 962-63 (quoting *Davies*, 930 F.2d at 1399).

The Fourth Circuit does not have any analogous case law interpreting *Rumery*. It has held that public policy is implicated only where "it is explicit, well defined and dominant, and ascertainable by reference to the laws and legal precedents and not from general considerations of supposed public interests." *L&E Corp. v. Days Inns of Am., Inc.*, 992 F.2d 55, 58 (4th Cir. 1993) (quotations and citations omitted). However, this applies to public policy concerns in the interpretation of a contract rather than in a determination of its validity. *Id.*

the public interest by diluting incentives to file qui tam suits, thus making the government less likely to learn of the alleged fraud, and by diluting the FCA's deterrent affect. The qui tam provisions are designed to supplement government enforcement of the FCA by using financial incentives to encourage insiders privy to fraud on the government to disclose this inside knowledge and potentially prosecute violations. *Id.* at 963. Relators, or private individuals who bring suits on behalf of the government, are entitled to a portion of the recovery from a qui tam suit, the amount of which depends on whether the government chooses to intervene after learning the allegations and prosecute the case itself and the overall importance of the relator's participation in the action. *Id.* at 963-64. Congress deemed this necessary because of reluctance on the part of insiders to come forward with relevant knowledge of fraud as well as federal enforcement agencies' relative lack of resources to investigate and prosecute allegations of fraud, leaving some potentially significant cases unaddressed. *Id.* at 963. Because a relator is only entitled to a portion of the proceeds from a successful qui tam suit, both the relator and the party accused of fraud could benefit financially by settling before the government learns of the allegations. The relator would likely be willing to accept a lower overall settlement amount from the other party, knowing that he would receive the entire amount, rather than only a portion of the settlement. *Id.* at 965-66. Thus, allowing

enforcement of such a release to bar a subsequent qui tam suit undermines the financial incentives thought necessary by Congress to ensure that those with inside knowledge file qui tam suits alerting the government of the alleged fraud and potentially assisting the government with its investigatory and prosecutory burden. *Id.* Further, because parties engaged in the fraud would be able to settle their claims with potential relators for significantly less than they would once the government became aware of the allegations, the FCA's deterrent effect is also lessened. *Id.*

The employer in *Green* argued that because the government had ultimately become aware of the allegations and conducted its own investigation, the release would not have detrimental effects. However, the Ninth Circuit noted that:

> the government only learned of the allegations of fraud and conducted its investigation *because of the filing of the qui tam complaint*. If the prevailing legal rule were that prefiling releases entered into without the government's consent or knowledge were enforceable, then it stands to reason that [the plaintiff-relator] never would have filed his *qui tam* complaint in the first place

and rejected this argument because of the *ex ante* effects of enforcing the agreement. *Id.* at 966.

Ultimately, the Ninth Circuit found that the significant public interests at issue when a potential relator and potential defendant execute a release, without the government's knowledge or consent, prior to the filing of a qui tam complaint

outweighed the general interest in settling litigation and determined that, as a rule, such pre-filing releases were not enforceable to bar the subsequent qui tam actions. *Id.* at 969.

Later, in *Hall*, the Ninth Circuit carved out an exception to the general rule against enforcing pre-filing releases to bar subsequent qui tam suits: where the government has full knowledge of the allegations and an opportunity to investigate these prior to the release, the release will be enforceable and will bar a later qui tam suit. 104 F.3d at 231. *Hall* involved an employer who had been accused of fraud on the government by an employee. However, after the employee raised these concerns, the employer contacted the regulatory agency involved and apprised them of the allegations. *Id.* That agency investigated and concluded that it could not substantiate the allegations. *Id.* at 231-32. During the course of the agency's investigation, the employee was terminated and initiated a state court action, which did not include a qui tam claim. *Id.* at 232. The state court action resulted in a settlement and general release, which was executed more than a year after the agency had completed its investigation. *Id.* Months later, the former employee filed a qui tam complaint in federal court. *Id.*

As in *Green*, the Ninth Circuit in *Hall* relied on the *Rumery* test, but concluded that the concerns that weighed against enforcement in *Green* were not present. *Id.* at

233. Notwithstanding the government's lack of knowledge of or consent to the release, because the federal government was already aware of the allegations of fraud, the public interest in having information disclosed to the government was not implicated. *Id.* Likewise, the public interest in using qui tam suits to supplement federal enforcement of the FCA was not disturbed as the government had already investigated the allegations prior to the release.[10] *Id.* Thus, the exception created by *Hall* provides that a release entered into after the government has full knowledge of the allegations and an opportunity to investigate will be enforced to bar a subsequent qui tam suit.

To determine whether the circumstances of a case fall within the general rule articulated in *Green* or the exception in *Hall*, the critical issue is the completeness of

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[10] It is not entirely obvious why the Ninth Circuit concluded that a full investigation negates the public interest in having a qui tam supplement federal enforcement, which includes not only disclosing information to the government, but also potentially investigating and prosecuting the case on behalf of the government. While this would seem to be the case in *Hall* since the federal government had not only completed its investigation, but concluded that the allegations could not be substantiated, this does not mean that there are not other cases that the government may have investigated fully but determined that it would not prosecute on its own for a variety of reasons, such as the low amount of money involved compared to the cost of prosecution, the low likelihood of success, or the lack of government resources to pursue it. It is important to note that the government's decision not to intervene "does not necessarily signal governmental disinterest in an action, as it is entitled to most of the proceeds even if it opts not to intervene." *DeCarlo*, 937 F. Supp. at 1047. In such cases, I can hardly think that the mere fact of a government investigation would negate the public interest in having a private citizen shoulder the burden of prosecution that would allow the government to recover monies lost through fraud.

the government's knowledge or the fullness of its investigation. *United States ex rel. McLean v. County of Santa Clara*, No. C05-01962 HRL, 2006 WL 2067061 (July 25, 2006) at *7 ("[T]he key question is whether the government knew about [the relator's] allegations of fraud and had an opportunity to investigate them before the release was executed."); *Longhi*, 481 F. Supp. 2d at 820 ("If there is a dividing line to be found between *Hall* and *Green*, it is the fullness of the government's investigation, not the timing of the release."). Partial knowledge or investigation on the part of the government is insufficient to remove a case from the purview of *Green* into the exception created by *Hall*.[11] *Bahrani*, 183 F. Supp. 2d at 1272. Evidence presented in *Bahrani* demonstrated that, prior to executing a general release, the relator had two brief conversations with an FBI agent prior in which he made charges

[11] Purdue contends that, under *Hall*, enforcement of a release to bar a subsequent qui tam action is appropriate even if the government has not completed its investigation. The citations it relies on to support this argument are inapposite or misleading. Purdue cites *Gebert*, 260 F.3d 909, in which the government did not investigate until after the filing of the qui tam complaint and the court ultimately chose to enforce the release. However, the decision to enforce the release turned on the fact that the release occurred "in the context of a bankruptcy proceeding, not through a general, independent release of a claim for money." *Id.* at 916. The court did not inquire into the fullness of the government's investigation. Purdue also argues that in *Hall* itself the government had not completed its investigation prior to the execution of the release. In *Hall*, the Nuclear Regulatory Commission ("NRC") completed and closed an investigation after the defendant made it aware of the relator's allegations, before the filing of the qui tam complaint. After the qui tam suit was initiated, the NRC revisited its prior investigation and reached the same conclusions. This is factually distinct from the situation in which the government is in the midst of an ongoing investigation.

against his employer but offered no specifics regarding the alleged fraud. *Bahrani*, 183 F. Supp. 2d at 1277. More than a year later, after he had executed the release, the relator was contacted by USDA investigators and at this time he provided detailed information regarding his allegations. *Id.* at 1277-78. In finding the release unenforceable, the court reasoned that the limited knowledge of the allegations held by the government did not negate the public interest in providing incentives for the relator to fully disclose inside information concerning the allegations to the government. *Id.* at 1278. It further reasoned that "[t]he public's interest in [the relator] maintaining the ability to bring a qui tam action to supplement federal enforcement of the FCA also remained as there was no guarantee when [the relator] executed the Release that the federal government was ever going to investigate, let alone prosecute," the alleged fraud. *Id. Longhi* involved a release executed eleven days after the relator filed a qui tam complaint. 481 F. Supp. at 817. The government began a lengthy investigation after the execution of the release and ultimately chose to intervene. *Id.* The court held the release unenforceable both because it was executed within the statutory sixty-day investigatory period and interfered with the government's ability to evaluate whether to intervene in the suit and because it was contrary to public policy under the *Green/Hall* framework. *Id.* at 818. In weighing the policy concerns under *Rumery*, the court emphasized that the government had

barely begun its investigation when the release was executed. *Id.* at 820. The government stated that without the relator's assistance following the release date it could not have issued a warrant to obtain documents or made sense of those documents when received and that given that these documents were not received until several weeks after the release date, the government had not had the opportunity to fully investigate prior to the execution of the release. *Id.* at 821.

Based on the evidence in the present case, it is clear that the government was aware of the substance of Radcliffe's allegations[12] and had begun, but not completed, its investigation of these allegations as of the date of the release. Radcliffe's allegations pertain to the issue of the relative cost and potency of OxyContin and MS Contin. Specifically, he alleged that Purdue fraudulently marketed OxyContin using the 2:1 equianalgesic ratio, thus claiming that its relative cost was less than that of MS Contin. Document production requests made by the government and

[12] The parties argue over whether *Hall* requires that the government know of the substance of the allegations (that is, the alleged wrongdoing itself) or whether the government must know of the actual allegations made by the relator (that is, the fact that the relator has alleged such wrongdoing). It is unclear from *Hall* whether the NRC was made aware of the identity of the specific person making the allegations when it first investigated the matter. The court stated that the defendant "informed the [NRC] of Hall's concerns," but it does not necessarily follow that in doing so Hall was identified to the NRC. *Hall*, 104 F.3d at 231. Subsequent cases have not addressed this type of argument. I think it is sufficient under *Hall* that the government know of the substance of the allegations. This furthers the public interests in encouraging a potential relator to disclose his allegations to the government as quickly as possible, before the government has an opportunity to discover the alleged wrongdoing through other means.

conversations between lawyers representing the government and Purdue or its employees in June and July of 2005 suggest that the government was trying to learn more about the relative cost and potency issue. Michael Scheininger, counsel to several Purdue employees, stated that Department of Justice lawyer Barbara Wells informed him on June 24, 2005, of her intent to ask several of his clients about the dispute over the relative potency of OxyContin and MS Contin, explaining that it related to the marketing and cost implications. By the end of July, the government had also begun drafting Grand Jury Subpoena 513 which included requests for all documents discussing the relative analgesic potency or safety of OxyContin and MS Contin. However, it is also clear from the evidence that the government continued to seek such information after the release had been executed on August 1, 2005. In September and December of 2005, the Department of Justice contacted Purdue with electronic search terms, some of which pertained to the relative cost and potency issue. On December 5, 2005, AUSA Mountcastle described the government's investigation as including "whether Purdue falsely marketed OxyContin as being twice as potent . . . and, accordingly, less expensive than MSContin" and the accuracy of "the 2:1 comparison of OxyContin to MSContin." (Mountcastle Decl. ¶¶ (c) and (f)(2)). This implies that the government was by that point aware of the substance of

allegations, but more importantly that those facets of their investigations were still ongoing, beyond the date of the release.

Purdue argues that, under *Rumery*, the circumstances present here do not implicate the public interests articulated in *Green*, do not outweigh the general interest in settling litigation, and, thus, support enforcement of the release to bar this qui tam suit. Specifically, they argue that, as here, where the government learned of the allegations independently and had already begun its investigation into the substance of the allegations prior to the date of the release, where the relator delayed in filing the qui tam complaint and attempted to settle with the defendants prior to doing so, and where the government ultimately chose not to intervene, enforcement of the release is appropriate. However, I believe that enforcing the release under these circumstances would substantially impact important public interests associated with the FCA.

Enforcement of a release to bar a subsequent qui tam suit implicates several articulated public interests. These include the public interest in having relators disclose inside information of alleged fraud to the government, in having relators supplement federal enforcement of the FCA by assisting the government in its investigation and prosecution or prosecuting the claim itself, and in deterring future

fraud against the government. *See Green*, 59 F.3d at 965-68; *Bahrani*, 183 F. Supp. 2d at 1278.

Here, it appears that the government did learn of the substance of Radcliffe's allegations independently and was interested enough in them to request documents pertaining to and question various Purdue employees about the relative cost and potency issue. However, the government ultimately took its investigation in a different direction, focusing on the misbranding of OxyContin as "less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications." (Information ¶ 20, United States v. Purdue Frederick Co., *supra.*) The final settlement in the criminal case did not contain any reference to the relative cost and potency issue and did not purport to settle Radcliffe's suit. As in *Bahrani*, when the release was executed there was no guarantee that the government would end up prosecuting based on the relator's allegations. The public interest in Radcliffe maintaining the ability to supplement federal enforcement of the FCA by prosecuting these allegations on behalf of the government remains.

Purdue argues that Radcliffe was a bad actor who waited to file his qui tam complaint and, prior to doing so, attempted to settle with Purdue in exchange for an investment in a company he was starting. The "John Femaledeer" emails indicate that Radcliffe did try to settle his claims with Purdue, but later retracted this offer after

being told by an attorney that qui tam claims could not be settled without the government's consent. Purdue's response was ambiguous, first stating that Radcliffe did not have legitimate claim, but if he thought he did he should make it, then expressing an interest in investing in Radcliffe's company.

With respect to Radcliffe's delay in filing his qui tam suit, I agree that this does weigh in favor of enforcement as a means to encourage relators to file quickly and disclose their allegations to the government as soon as possible. However, Radcliffe did file while the government was still investigating and when he could potentially still have been of use to the government. With respect to the settlement attempts, it would seem counterintuitive to enforce a release to bar a subsequent qui tam suit, thus foreclosing the relator's ability to prosecute on behalf of the government, to punish that relator for trying to settle instead of filing suit in the first place. Were this the rule, a relator who initially tried to settle would have no incentive to disclose the allegations to the government in lieu of settlement. As a result, such a rule would reward potential defendants who encourage settlement and would impair the public interest in having relators disclose information to the government.

Finally, the government's decision not to intervene in this suit, announced on May 8, 2007, should not be a basis for enforcement of the release. *See DeCarlo*, 937

F. Supp. at 1047.[13] The government's decision not to intervene "does not necessarily signal governmental disinterest in an action, as it is entitled to most of the proceeds even if it opts not to intervene." *Id.* Enforcing a release in this situation would deprive the public of a potential relator to enforce the FCA and recover monies for the government treasury. This rule would also make the enforcability of such a release dependant on the government's intervention decision and may discourage some potential relators from initiating qui tam suits in the first place, leaving some allegations undisclosed. *See id.* Further, such a rule would mean that the enforceability of the release would be uncertain until such time as the government chose whether to intervene, which would undermine the countervailing interest in settlement of litigation.

Accordingly, I find that under these circumstances, enforcement of the release would undermine important public interests associated with the FCA, as well as the countervailing interest in settling litigation. The generalized interest in settling litigation is outweighed in the present circumstances by public interests that would be impaired by enforcement of this release, and so analysis under the *Rumery* test does not favor enforcing Radcliffe's release.

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[13] *But see United States ex rel. Whitten v. Triad Hosps., Inc.*, No. CIV.A. CV202-189, 2005 WL 3741538, at *5 (S.D. Ga. Oct. 27, 2005) (citing *DeCarlo* for the opposite conclusion).

The circumstances here fall within the general rule articulated in *Green* that pre-filing releases are unenforceable to bar subsequent qui tam actions, rather than the *Hall* exception, because the government had not fully investigated the substance of Radcliffe's allegations. Further, the public policy concerns raised by Purdue do not alter the relative balance of public interests under the *Rumery* test. The general release executed by Radcliffe does not bar this action.

IV. RULE 9(B) REQUIREMENT.

Purdue argues that Radcliffe has failed to plead fraud with particularity as required by Federal Rule of Civil Procedure 9(b).

Lack of compliance with the pleading requirements of Rule 9(b) is treated as a failure to state a claim under Rule 12(b)(6). *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 n.5 (4th Cir. 1999). With respect to allegations of fraud, "the 'circumstances' required to be pled with particularity under Rule 9(b) are 'the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby.'" *Id.* (quoting 5 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1297, at 590 (2d ed. 1990)).

After carefully considering the arguments of the parties, I hold that the Complaint does not adequately state a claim for fraud under Rule 9(b).

In his Complaint, Radcliffe alleges that Purdue "encouraged physicians to write prescriptions that were paid by Medicaid and other government programs for OxyContin that was materially less potent . . . and as a result, generally more expensive than the OxyContin that was described in [Purdue's] marketing pitch to the same physicians." (Third Am. Compl. ¶ 30.) Radcliffe also avers that

> Relator cannot identify at this time all of the false claims which were caused by Purdue's conduct. The false claims were submitted primarily by pharmacists as a result of the fraudulently induced prescriptions (who apparently did not know they were false) with whom the Relator had no dealings and the records of the false claims are not within the Relator's control. Indeed, specification of the vast amounts of false claims would be burdensome to the Court and the parties. Given the vast number of false claims, their scope and complexity, Relator is excused from the requirement of specifying each false claim. Such claims were made across the entire United States.

(*Id.* at 36.)

While Purdue concedes that a defendant may be liable for inducing a third party to submit a false claim to the government, it argues that Radcliff's allegations do not meet the Rule 9(b) pleading requirements because he does not describe even a single instance in which a physician was influenced to prescribe OxyContin based

on Purdue's misrepresentations, and where a claim for payment was made by the pharmacist to the government. I agree.

Of course, it is plausible that a physician would be so induced by false representations concerning OxyContin's relative potency to write a prescription, ultimately paid for by the government. But that is not sufficient to meet the rigorous standard of Rule 9(b). *See United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007).

Radcliffe requests that if the Complaint is found insufficient on this ground, that he be granted leave to file an amended complaint. Purdue objects, but I find no cognizable basis for denying Radcliffe's request. *See id.* at 733-34 (remanding to allow leave to amend).

V. CONCLUSION.

For the reasons stated, the Motion to Dismiss will be denied in part and granted in part, with leave to amend.

A separate order will be entered herewith.

DATED: October 14, 2008

/s/ James P. Jones
Chief United States District Judge